REMARKS/ARGUMENTS

The Office Action mailed July 23, 2003 has been reviewed and carefully considered. Claims 1, 10, 11, and 12 have been amended. Claims 16-19 are added. Claims 1-19 are pending in this application, with claims 1, 10, 11, and 13-15 being the only independent claims. Reconsideration of the above-identified application, as herein amended and in view of the following remarks, is respectfully requested.

Drawings

In the Office Action mailed July 23, 2003, the Examiner indicates that the proposed drawings filed on May 15, 2003 are approved and that a proper drawing correction or corrected drawings are now required. Attached hereto is a corrected version of Fig. 1.

Claim objections

Claims 1-9, 11-13, and 15 are objected to because "the end zone of the medical instrument" in claim 1, lines 5-6 lacks antecedent basis. The Examiner also states that claim 11 is incomplete in that it does not recite any structure of a medical instrument. Claims 1 and 11 are amended to address these concerns. In view of the above amendments, it is respectfully requested that the objections to the claims now be withdrawn.

Rejections under 35 U.S.C. §112, first paragraph

Claims 13-15 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that is not adequately described to enable one skilled in the art to make and/or use the invention. More specifically, the Examiner states that the specification fails to disclose a computer program with section for executing the method set forth in the claims. As cited in the MPEP §2106.01, "As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of

the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. . . . [F]low charts or source code listings are not a requirement for adequately disclosing the functions of software." *Fonar Corp.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (citations omitted). Accordingly, it is respectfully submitted that a disclosure of the actual code or program steps is not required. The specification of the above-referenced application adequately discloses the functions of the software and therefore provides an adequate written description of the computer software. In view of the above amendments and remarks, it is respectfully requested that the rejection of claims 13-15 now be withdrawn.

Rejections under 35 U.S.C. §103

Claims 1, 2, 5, 9-11, and 13-15 stand rejected as unpatentable over U.S. Patent No. 5,638,819 (Manwaring). Claims 3 and 12 stand rejected as unpatentable over Manwaring in view of U.S. Patent No. 5,951,472 (Van Vaals). Claim 4 stands rejected as unpatentable over Manwaring in view of U.S. Patent No. 6,266,552 (Slettenmark). Claims 6 and 12 stand rejected as unpatentable over Manwaring in view of U.S. Patent No. 6,275,724 (Dickenson) or U.S. Patent Application Publication No. 2002/0165448 (Ben-Haim). Claim 7 stands rejected as unpatentable over Manwaring in view of U.S. Patent No. 6,498,948 (Ozawa). Claim 8 stands rejected as unpatentable over Manwaring in view of U.S. Patent No. 6,023,636 (Wendt).

Before discussing the cited prior art and the Examiner's rejections of the claims in view of that art, a brief summary of the present invention is appropriate. The present invention relates to a method for determining the position of a medical instrument introduced into an object, i.e., a patient, to be examined and for imaging the vicinity of the medical instrument. More specifically, the present invention relates to determining the position of a flexible medical

instrument introduced into the object (see page 2, lines 15-19 of the speicification). An end zone of the medical instrument includes an image acquisition device 4 and localization device 5 (page 5, lines 12-14). As shown in Fig. 1, the end zone is a section of the medical instrument that is proximate the tip that is inserted into the object.

The localization device 5 cooperates with a coil array 7 arranged beneath the patient (page 5, lines 20-26). Accordingly, the position of the end zone relative to the coil array can be determined. The image acquisition device 4 supplies image information concerning the vicinity of the image acquisition device 4 (page 5, lines 14-19).

A data processing device 12, determines, from the data received from the localization device 5 and the image acquisition device 4, a position of the localization device, i.e., the end zone of the medical instrument, in relation to a survey image defined by a stored image data set of the examination zone of the patient (page 6, lines 6-8). The image set may be formed directly before intervention or during an earlier diagnosis and is stored in a database 13 (page 6, lines 8-10). The image set may be four-dimensional with a temporal resolution such that different image sets may be obtained at different instants during cardiovascular motion phase (see page 3, lines 3-8). To determine the position of the end zone relative to the survey image in database 13, registration by suitable markers on the patient which are also present in the survey image is required (page 6, lines 10-14). The data processing device displays the survey image on a monitor 14 and the position of the end zone is superposed thereon (page 6, lines 16-19). The image from the image acquisition device 4 may also be displayed on the monitor 14 simultaneously (page 6, lines 19-22). Sensors measuring respiratory and/or cardiac motions may be used to compensate these motions during localization and imaging.

Manwaring discloses a medical instrument in which a sensor 30' is coupled to a localizer 26 for providing location of the medical instrument. Manwaring requires that a probe tip 36 of the medical instrument has a fixed spatial relationship to the sensor so that the location of the probe tip is definitely known based on the pitch, roll and yaw signals from the sensor 30' (see col. 4, lines 24-28). The Examiner states that it would have been obvious as an engineering design choice to place the sensor 30' at the tip. However, it is respectfully submitted that Manwaring fails to teach or suggest that the sensor 30' can be located on the end zone of the instrument that is inserted into the patient. In contrast, Manwaring shows the sensor 30' as external to the probe which would prevent it from being arranged in the end zone of the probe. Manwaring requires a complex sensor which indicates pitch, roll, and yaw so that the location of the tip of the instrument can be determined. Manwaring would have installed a sensor in the tip if it was possible to avoid using the complex sensor. These disclosures of Manwaring actually teach away from installing a sensor in the probe tip. Accordingly, it is respectfully submitted that Manwaring fails to teach or suggest a localization device arranged in the end zone of the medical instrument that is inserted in the patient, as recited in independent claims 1, 10, 11, and 13-15.

Manwaring also discloses that tomographic data may be saved in a memory (see col. 3, lines 55-60). This data may be displayed such as reference character 42 in Fig. 1. However, Manwaring does not show the current position of the medical instrument relative to the tomographic slice (see Fig. 1). In contrast, the tomographic slice shown only a desired trajectory 54. Accordingly, Manwaring fails to teach or suggest superposing the actual position of the medical instrument on a survey image, as recited in independent claims 1, 10, and 13-14. In contrast, Manwaring discloses a separate indication of the probe position relative the desired target location in reference character 46.

Furthermore, Manwaring fails to teach or suggest that the tomographic data includes indications of markers on the patient. Rather, Manwaring uses only data from sensors 30 arranged on the patient. Accordingly, Manwaring teaches away from including indications of markers in the survey image, as recited in independent claims 1, 10, and 13-14.

Manwaring also fails to teach or suggest using markers to determine a position of the medical device in the survey image. Rather Manwaring discloses that the roll, yaw, and pitch are used to verify that the probe trajectory matches a target projectory. In view of the above remarks, Manwaring fails to teach or suggest reproducing the position of the medical instrument on the survey image based on the position determined and the markers on the patient as recited in independent claims 1, 10, and 13-14.

In view of the above amendments and remarks, it is respectfully submitted that independent claims 1, 10, 11, and 13-15 are allowable over Manwaring. Dependent claims 2-9, 12, and 16-20, each being dependent on one of independent claims 1, 10, and 11, are allowable for the same reasons as are independent claims 1, 10, and 11.

The application is now deemed to be in condition for allowance and notice to that effect is solicited.

It is believed that no fees or charges are required at this time in connection with the present response; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,

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By _____

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